## Remarks

Claims 1, 3-6, 8, and 11-14 were pending in the subject application. By this Amendment, the applicant has amended claim 1 and added new claim 22. Accordingly, claims 1, 3-6, 8, 11-14 and 22 are presented for consideration by the Examiner.

Support for the amendments set forth herein can be found throughout the subject specification including, for example, page 3, lines 25-27, and page 4, lines 3-6. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein is earnestly solicited.

Claims 1, 3-5, 8 and 11-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,734,398 or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,734,398 (the '398 patent is referred to hereinafter as "diZerega"). Also, claims 1, 3-6, 8 and 11-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,734398.

The Opinion of the Board of Appeals (herein after the "Board Opinion") is clear that the basis upon which the prior art rejections were previously based has been vacated. Specifically, the Board's Opinion acknowledges that diZerega's FRP is <u>not</u> micrin. See page 9 of the Opinion. The Board indicated, however, that the applicant's claimed fraction could conceivably inherently contain minute amounts of micrin that had gone unnoticed by diZerega.

To eliminate the possibility that the applicant's claims could possibly read on the diZerega composition, the applicant's claims have been amended herein to specifically require that the micrin obtained according to the subject invention has a specific activity of at least 1 unit/ml. The applicant has also added a claim to purified micrin.

The applicant respectfully points out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the process or method claimed. *In re King*, 801 F2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available <u>only</u> when the prior inherent event can be established as a <u>certainty</u>. That an event <u>may</u> result from a given set of circumstances is

not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

Keeping in mind the patent law as it relates to inherency, there is no doubt that the diZerega composition does not have sufficient micrin to meet the limitations of the applicant's claims as amended herein.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, <u>disclosure of each and every element of the claimed invention</u>, <u>arranged as in the claim</u>.

Connell v. Sears Roebuck and Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); SSIH Equip. S.A. v. USITC, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. SSIH, supra; Kalman [v. Kimberly-Clarke, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In the present case, as discussed above, the diZerega composition does not meet all of the limitations of the composition claimed by the current applicant. Therefore, there can be no anticipation.

Furthermore, it is well established in the patent law that the mere fact that the purported prior art <u>could</u> have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_ (2007).

In the current case, there is no reason or teaching that would direct the skilled artisan to the claimed composition.

Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejections based on the diZerega reference.

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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